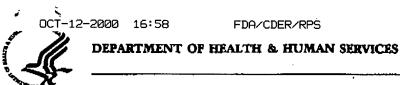
Public Health Service



AUG

Food and Drug Administration Rockville MD 20857

> Re: Xenical® Docket No. 00E-1413

The Honorable Q. Todd Dickinson Director of U.S. Patent and Trademark Office Commissioner for Patents Box Pat. Ext. Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,598,089 filed by HLR Technology Corporation under 35 U.S.C. § 156. The human drug product claimed by the patent is Xenical® (orlistat), which was assigned new drug application (NDA) No. 20-766.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on April 23, 1999, which makes the submission of the patent term extension application on May 21, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Associate Director for Policy

Center for Drug Evaluation and Research

George W. Johnston CC: **HLR Technology Corporation** Patent Law Department 340 Kingsland Street Nutley, NJ 07110